



4 October 2023

Medicine Supply Alert Notice

Disopyramide (Rythmodan®) 100mg capsules

Priority: Level 2*

Valid until: late October 2023

Issue

1. Disopyramide (Rythmodan®) 100mg capsules are out of stock until late October 2023.
2. Disopyramide (Rythmodan®) 250mg prolonged release tablets are out of stock until mid-December 2023 but parallel imports remain available and can fully cover demand.
3. Limited stock of parallel imports of disopyramide 100mg are available and can partially cover demand for 100mg capsules.
4. Unlicensed imports of disopyramide 100mg capsules and disopyramide 250mg prolonged release tablets have been sourced, lead times vary (see Additional information).

Advice and Actions

5. Prescribers and pharmacy teams should:
 - identify patients prescribed disopyramide 100mg capsules and establish if they have sufficient supply to last until the resupply date; and
 - reserve remaining supply of 100mg disopyramide capsules for these patients with insufficient supply.
6. Where licensed disopyramide 100mg capsules are unavailable:
 - consider prescribing unlicensed imports of disopyramide 100mg capsules, taking into account lead times;
 - if the above option is not possible due to lag time in obtaining supply, convert patients to disopyramide 250mg prolonged release tablets at same total daily dose, if the formulation allows, or as close a dose as possible, and titrate dose as needed (see Additional information);
 - where licenced (parallel import) disopyramide 250mg prolonged release tablets are unavailable, consider prescribing unlicensed imports, taking into account lead times; and
 - seek advice from cardiology specialists on management of unstable patients or patients newly started on treatment, or where there is uncertainty or concern about switching formulation and or/dose conversion.

7. For patients commencing treatment with disopyramide, prescribers should:
 - not prescribe 100mg capsules until the shortage has resolved and consider initiating patients on disopyramide 250mg prolonged release tablets; and
 - if the above option is unsuitable, consider prescribing unlicensed imports of disopyramide 100mg capsules, taking into account lead times.
8. Patients should be counselled on any change in formulation and/ or dose change and advised to report adverse effects and/or recurrence of symptoms after switching. When patients are changed to prolonged release tablets, they should be reminded that tablets should be swallowed and not crushed or chewed.

Additional Information

Clinical Information

9. Disopyramide is licensed for the treatment of cardiac arrhythmias, with dose adjusted according to response. In addition to the immediate release capsule formulation, it is also formulated as a prolonged release tablet. As disopyramide tends to be a last line antiarrhythmic agent, alternative treatment options are limited, and require specialist input.

Dosing information

Disopyramide

Half-life: 5 to 8 hours

Immediate release capsules (100 mg)

Licensed dose range: 300 mg to 800 mg daily in divided doses (usually every 6 to 8 hours)

Prolonged-release tablets (250 mg)

One side has a break-line and the tablets are licensed to be halved.

Licensed dose range: 250-375 mg (one to one and a half tablets) twice daily.

Switching

10. The total daily dose of the 100mg immediate release capsules should be converted to the closest equivalent dose of the prolonged release tablets, administered twice daily. A decision will have to be taken on whether to go under or above current dose for those patients on doses that cannot be exactly delivered by the prolonged release tablets. In practice, lower dose conversions are likely to be used and the dose titrated up as needed, based on response and tolerability.

Immediate release capsules total daily dose (mg)	Prolonged release tablet dose regimens (mg)	Prolonged-release tablet total daily dose after switch (mg)
300	125 twice daily or 250 am and 125 pm	250 or 375
400	250 am and 125 pm or 250 twice daily	375 or 500
500	250 twice daily	500
600	375 am and 250 pm	625
700	375 twice daily	750
800	375 twice daily	750

Guidance on ordering and prescribing unlicensed imports

11. The following Specials manufacturers have confirmed they can source unlicensed disopyramide 100mg capsules (please note there may be other companies that can also source supplies):
 - Alium
12. The following Specials manufacturers have confirmed they can source unlicensed disopyramide 250mg tablets (please note there may be other companies that can also source supplies):
 - Maudsley
13. Any decision to prescribe an unlicensed medicine must consider the relevant regulatory, professional and Board guidance and local governance procedures. Please see the links below for further information:
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC)

Links:

- [Disopyramide preparations](#)
- [BNF disopyramide](#)

Specialist Pharmacy Service (SPS) website

14. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.
15. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
16. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
17. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

18. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).